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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/699,716	08/27/96	HEATH	D 003/029/SAP

HM22/0912

US ARMY MEDICAL RESEARCH &
MATERIAL COMMAND
ATTN MCMR JA JOHN MORAN
FORT DETRICK FREDERICK MD 21702-5012

EXAMINER	
DUFFY, P	
ART UNIT	**PAPER NUMBER**
1645	20

DATE MAILED: 09/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)	
08/699,716	Heath	
Examiner	Group Art Unit	
Duffy	1645	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 6-30-00.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-3, 5-32 is/are pending in the application.

Of the above claim(s) 18-29 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5-17, 30-32 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-3, 5-32 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Response to Amendment

1. The amendment filed 6-30-00 has been entered into the record. Claims 1-3, 2-28, 29-32 are pending and under examination.

2. This application contains claims 18-29 are drawn to an invention nonelected with traverse in Paper No. 7, received 8-11-97. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Objection / Rejections Withdrawn

4. The amendment filed 8-11-97 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention is withdrawn based on applicants amendment to restore the original subject matter.

5. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn based on applicants amendment.

Rejections Maintained

6. The rejection of claims 31 and 32 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons made of record in Paper No.17, mailed 2-1-00.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that claim 24 recites an FI-V protein with the particular recited combination of any V-antigen homolog. Original claim 24, recites "A vaccine for *Yersinia* infections comprising a FI-V protein comprising all or a portion of FI capsular antigen of *Yersinia pestis* **and** [emphasis added] all or a portion of V antigen of *Yersinia pestis* **and** [emphasis added] all or a portion of *Yersinia enterocolitica* V antigen **and** [emphasis added] all or a portion of *Yersinia pseudotuberculosis* V antigen capable of eliciting protective antibodies against Yersinia infection in a pharmaceutically acceptable excipient in a pharmaceutically acceptable amount." The protein as claimed would be a combination of FI and all three V antigens or portions of all there V antigens. Applicants indicate that the V antigens are recited in the alternative. This is simply not so. Applicants also argue page 13, lines 13-17 to indicate that the "V-antigen" of the FI-V protein may alternatively contain the V-antigens from *Yersinia enterocolitica* or *Yersinia pseudotuberculosis*. Claim 24 in light of the recitation at page 13, that the FI-V protein comprising all or a portion of FI capsular antigen of *Yersinia pestis* **and** [emphasis added] all or a portion of V antigen of *Yersinia pestis* may also contain V-antigens from *Yersinia enterocolitica* or *Yersinia pseudotuberculosis* is seen to provided for the addition to the V-antigen from *Yersinia pestis*, not the alternative as applicants suggest.

The rejection is maintained.

7. The rejection of claim 11 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn over claim 15 only, the rejection over claim 11 is maintained for reasons made of record.

The examiner acknowledges that Applicants will deposit the plasmid and will provide the deposit information when it becomes available. Until such time as the deposit requirements have been met, the rejection is maintained.

8. The rejection of claims 31-32 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons made of record in Paper No. 8, mailed 11-10-97.

The rejection is maintained. No *Yersinia* DNA homologues are described in the specification. Applicants amendments are insufficient to remove this rejection as it applies to claims 31 and 32.

9. The rejection of claims 1-3 and 5-17, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/18231 (Titball et al.-31) and further in view of: WO 95/24475 (Titball et al.-'75); or Leary et al. Infection and Immunity 63(8): 2854-58 8/95, publicly available as of 7/25/97) is maintained for reasons made of record in Paper No. 17, mailed 2-1-00.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that fusions with respect to immunogenic portions of the antigenic proteins are unpredictable because many parameters require consideration and testing such as the site of fusion, the order of fusion, whether the complete protein or antigenic portions should be fused, weather the fusion protein will fold properly and retain antigenicity. These arguments are not

persuasive, the art has demonstrated that each of the claimed FI and V antigens (i.e. not portions thereof) have been produced as fusion proteins and retain their antigenicity. Applicants also argue that immunogenic portions are unpredictable because it is undue experimentation to produce a fusion protein which retains immunogenic characteristic of each of the fused partners. This is not persuasive because (a) the claims are not drawn to small portions of the FI of V antigens, while the art speaks to unpredictability of small epitopes, it does not speak to unpredictability of the large protein and (b) the claims merely require antigenicity, not retaining the original immunogenic character of the unfused partner. Applicants appear to argue that the art in production of fusion proteins is so unpredictable, that until one has produced and tested a fusion protein as a vaccine the art can not be enabling. Are applicants therefore inviting an enablement rejection? It is noted that applicants own specification teach but a single effective fusion protein (SEQ ID NO:2). If the art is so unpredictable, then applicants own specification is only enabled for the specific working embodiment and nothing broader. Applicants arguments are again not persuasive, the uncertainty with respect to small portions is not seen to be dispositive in the instant case because the claims are not drawn to small portions of the FI or V antigens. Moreover, each of these antigens were produced as stable fusion proteins and both are antigenic as fusion proteins, not as immunogenic peptides. It is the immunogenic peptides which are unpredictable, not the immunogenic proteins of the prior art as combined. WO 95/18231 (Titball et al.-31) teach that the FI has been demonstrated to be protective and that the fusion construct when administered as a whole cell vaccine provided protection (see page 2, first full paragraph; page 3, second full paragraph; page 5; second full paragraph and page 11, table 1 pFSIG3(a)). The conclusion is that the fusion protein expressed by the whole cell retained its antigenicity. WO 95/24475 (Titball et al.-'75) at page 3, first full paragraph state that the

polyclonal antisera raised against the antigen fusion (PAV) were partially protective. Thus, it is clear that the fusion protein of Titball -75 retains protective antigenicity. Thus, applicants argument regarding the stability of fusion proteins are not persuasive since the fusion proteins of F1 and V of the art were stable and conferred protection. Thus, the production of a fusion protein comprising "all of the F1 and V antigens" would be reasonably be expected to be stable, antigenic and the individual fusion proteins were demonstrated by the art to induce a protective response. Applicants allegation of the fusion of the F1 antigen with a portion of the V antigen are also not persuasive since the claims are drawn to "all of" the F1 and V antigen and not small portions thereof.

The rejection is maintained.

Status of Claims

10. All claims stand rejected.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
September 11, 2000

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600